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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,489	01/23/2001	Lisa Joanne Drewe	41577/252464	5644

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EXAMINER	
SIEW, JEFFREY	
ART UNIT	**PAPER NUMBER**
1637	9

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/744,489	Applicant(s) DREWE ET AL.	
	Examiner Jeffrey Siew	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 1999* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The key in Figure 2 does not appear to follow the drawing or does not satisfactorily elucidate the drawing. Correction is required.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. A formal amendment inserting the page with only the abstract is required.

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

4. As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables

having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

5. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 recites the purine rich limitation already recited in claim.1.

6. On page 5 line 32 polypyrimidine is misspelled.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 & 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 13 provides for the use of a primer, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

B) Claim 17 is indefinite because it is unclear what limitations are imparted on the claim by the phrase "substantially as hereinbefore described".

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3-8, 12-14 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary (WO 92/11390 9 July 1992) in view of Ecker et al's(US5,641,625 June 24, 1997).

Vary et al teach the use of a probe for detection nucleic acid sequence target by formation of triple helix which eliminates denaturation during detection (see whole doc. esp. abstract) . They teach detection of amplification of product duplexes. The triple helix forming duplex sequences may be endogenous to target sequence or they may be introduced by probes during PCR amplification by primers. The target sequence containing polypurine region (see page 5 lines 20 & 21) and the probe contains high polypyrimidine (see col. 4 line 25). They teach introducing polypyrimidine on 5' end of primer to introduce high polypurine target into

amplified DNA (see page 30 line15-20). They teach detection on electrophoretic gel (see example 1).

Vary et al do not teach peptide nucleic acid.

Ecker et al teach PNA probes which bind with high stability and specificity to double stranded DNA (see whole doc. esp. col. 4 line 4 line 47 & col. 15 line 1-5 & col. 4 line 35).

One of ordinary skill in the art would have been motivated to apply Ecker et al's PNA probes to Vary et al's detection method in order to provide a probe that binds specifically to target sequence. It would have been prima facie obvious to apply Ecker et al's probe to specifically discriminate target sequence in Vary et al's amplification product.

Moreover, it would have been prima facie obvious to combine all the reagents i.e. Ecker et al's PNA probe and Vary et al's primers to perform the triple helix detection method into a single kit in order for the practitioner to perform the method efficiently.

9. Claims 9-11, 15 & 16are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary (WO 92/11390 9 July 1992) in view of Ecker et al's(US5,641,625 June 24, 1997) in further view of Wang et al (J. Am Chem . Soc. Vol. 118 pp. 7667-7670 1996).

The teachings and suggestions of Vary and Ecker et al are described previously.

Vary do not teach a biosensor.

Wang et al teach biosensor attached PNA probes for detection. (see whole doc. esp. abstract).

One of ordinary skill in the art would have been motivated to apply Wang et al biosensor PNA surface probes to the combined invention of Vary and Eckert et al detection method in

order to increase the high throughput and sensitivity of detection. Wang et al state that PNA biosensors provide faster hybridization and provided high sequence sensitivity without stringent control off hybridization conditions (see page 7670). It would have been prima facie obvious to apply Wang et al's biosensor to the Vary and Eckert et al's detection method in order to increase sequence sensitivity and high throughput analysis.

10. Claims 1-8, 13, 14 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary (WO 92/11390 9 July 1992) in view of Frank-Kamenetskii et al (WO97/14793 24 April 1997)

Vary et al teach the use of a probe for detection nucleic acid sequence target by formation of triple helix which eliminates denaturation during detection (see whole doc. esp. abstract) . They teach detection of amplification of product duplexes. The triple helix forming duplex sequences may be endogenous to target sequence or they may be introduced by probes during PCR amplification by primers. The target sequence containing polypurine region (see page 5 lines 20 & 21) and the probe contains high polypyrimidine (see col. 4 line 25). They teach introducing polypyrimidine on 5' end of primer to introduce high polypurine target into amplified DNA (see page 30 line15-20).

Vary et al do not teach bis-peptide.

Frank-Kamenetskii et al teach a bis-PNA fro binding to double stranded DNA (see whole doc. esp. abstract). They teach that PNA clamps show high stability and may be used in PCR to avoid competing side reactions such as amplification of non target sequences in background and primer oligomerization.

One of ordinary skill in the art would have been motivated to apply Frank Kamenetskii et al's PNA probes to Vary et al's detection method in order to provide a probe that binds specifically to target sequence. It would have been prima facie obvious to apply Ecker et al's probe to enhance detection target sequence in Vary et al's amplification product.

SUMMARY

11. No claims allowed.

CONCLUSION

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Monica Graves for Art Unit 1637 whose telephone number is (703)-306-2938.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

JEFFREY SIEW
PRIMARY EXAMINER

June 29, 2002